

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

MEDICARE ANTIGEN PREPARATION



JANET REHNQUIST
Inspector General

October 2002
OEI-09-00-00530

Office of Inspector General

<http://oig.hhs.gov>

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Memorandum

Date ¹⁵ Debra Robinson
From Director, Regional Operations
Office of Evaluation and Inspections

Subject: OIG Memorandum Report: "Medicare Antigen Preparation," OEI-09-00-00530

To Jacquelyn Y. White
Director, Office of Strategic Operations and Regulatory Affairs
Centers for Medicare & Medicaid Services

Attached is a memorandum report that determines whether the Centers for Medicare & Medicaid Services' (CMS) reimbursement policy for the provision of antigens for allergen immunotherapy accurately reflects the resources used in a typical physician's practice. We surveyed immunotherapy providers to determine their typical practice and compared this with current practice expense inputs. We also assessed guidance provided by CMS to providers about changes to immunotherapy billing and payment policy.

Our inspection revealed that CMS did not have accurate data when the agency calculated the practice expense component for CPT code 95165, *professional services for the provision of antigens for allergen immunotherapy, single or multiple antigens, per dose*, as redefined in the November 1, 2000, *Federal Register*, effective January 1, 2001. While a typical physician administers 0.5 cc injections from 5 cc vials containing 8 antigens and 41 percent diluent, CMS calculated practice expense assuming 1 cc injections from 10 cc vials containing 5 antigens and no diluent. In addition, providers say that creating a dose of CPT code 95165 requires more time, 3.0 minutes, than allotted by CMS' calculation, 2.2 minutes. Furthermore, physicians do not think of a dose of immunotherapy in the same terms as defined by regulation, and almost 20 percent of them have changed the way they practice medicine, which is an unintended result of the policy change.

We conclude that although the inputs for the code should be refined, there is no compelling need for immediate change. Therefore, CMS could use this data and information as part of their normal process for refining practice expense inputs. In accordance with a CMS staff request, we will send the report to the Practice Expense Advisory Committee. If any new guidance is issued, CMS could continue to emphasize to physicians that they only need to modify their billings to comply, not the way they deliver immunotherapy.

You are welcome to provide comments but are not required to do so, since the report contains no recommendations. If you have any questions about this report or would like a meeting to discuss more detailed information, please have your staff contact Stuart Wright, Director, Medicare and Medicaid Branch at (410) 786-3144.

Attachment

OCTOBER 2001
OEI-09-00-00530

EXECUTIVE SUMMARY

OBJECTIVE

To determine if the Centers for Medicare & Medicaid Services' (CMS) reimbursement policy for the provision of antigens for allergen immunotherapy accurately reflects the resources used in a typical physician's practice.

BACKGROUND

Allergies, hypersensitive immune reactions to substances that are otherwise harmless, afflict one in six Americans. Substances which can trigger allergies are called antigens, and include such things as dust, molds, and pet dander. Symptoms range from mild irritation to life-threatening anaphylaxis. Medicare pays for the treatment of allergies through allergen immunotherapy, or allergy shots. In this therapy, a physician administers gradually increasing concentrations of an antigen in order to desensitize the patient. Treatment generally lasts from 3 to 5 years.

The preparation of antigens for allergy shots, but not the injection itself, is billed under Current Procedural Terminology (CPT) code 95165, *professional services for the provision of antigens for allergen immunotherapy; single or multiple antigens, per dose*. Traditionally, a dose was defined as the amount of serum administered in each allergy shot. In 1998, the CMS revised the definition to be the total amount of serum delivered each treatment session, regardless of the number of shots. After receiving many comments from specialty organizations, the CMS changed the definition in the November 1, 2000 *Federal Register*, effective January 1, 2001, to "a one cc aliquot [part] from a single multidose vial."

We conducted a survey of a stratified random sample of 306 physicians who provide allergen immunotherapy. We received responses from 186 of these for a response rate of 60.8 percent. In addition, we conducted follow-up interviews with several sample physicians, interviewed and reviewed documentation from 25 of 27 Medicare carriers, and reviewed the Medicare law, regulation, and policy related to CPT code 95165.

FINDINGS

Resources used in allergen immunotherapy differ from CMS assumptions

Based on our analysis, we found that data used by CMS to calculate practice expense inputs for CPT code 95165 are not accurate. The CMS estimates that in a typical practice, physicians provide immunotherapy from 10 cc multidose vials in shots of 1 cc each. We found that the median vial size is 4.9 cc and the median injection volume is 0.47 cc. In addition, while the current calculations assume 5 antigens are in each vial of immunotherapy, we found that a typical vial contains approximately 8 antigens. Lastly, while the new definition of a dose incorporates 2.2 minutes of clinical staff time, our research indicates that each dose requires 3.0 to 4.5 minutes to prepare. Practice expense calculations for CPT code 95165 do not factor in the dilution boards the typical provider creates, but the allocation per unit for this expense would probably be minimal.

Almost 75 percent of providers are aware of the new definition of a dose

Nearly three-quarters of immunotherapy providers know about the revision, mainly through their specialty society. However, only 44 percent of all immunotherapy providers have changed their billing as a result. In addition, although the revision was intended for practice expense calculation and billing purposes only, approximately 14 percent of immunotherapy providers have begun giving 1 cc injections or changed other practice patterns. Providers generally prefer the traditional definition of a dose as the amount of antigen given in a single injection over the current or an alternate definition.

CONCLUSION

Based on our analysis of data and information from a random sample of allergists, we conclude that CMS did not have accurate data when it calculated the practice expense component for CPT code 95615. After consulting with CMS, we conclude that CMS should use this report to help refine the practice expense inputs for this code as part of their normal process rather than making an immediate change. Since some physicians modified their practice based on the changes in reimbursement, CMS should emphasize that physicians need modify only their billing to comply with the new definition in any guidance it plans to offer in the future. We also noted that most physicians rely on their specialty societies, rather than CMS or its carriers, for information about Medicare policy changes. Therefore, to ensure physicians are getting accurate information, CMS and the carriers may want to work directly with the societies to explain any policy changes and revisions.

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INTRODUCTION

OBJECTIVE

To determine if the Centers for Medicare & Medicaid Services' (CMS) reimbursement policy for the provision of antigens for allergen immunotherapy accurately reflects the resources used in a typical physician's practice.

BACKGROUND

Allergies and Their Treatment

Allergies afflict one in six Americans. People with allergies experience hypersensitive immune system responses to substances, called *allergens*, which are harmless to non-allergic people. Common allergens include pollen, mold, and animal dander. Allergens are a type of *antigen*, which is any foreign substance which triggers an immune response, including substances which are universally harmful like pathogenic viruses and bacteria. Allergy symptoms range from mild irritation to anaphylaxis, a medical emergency involving an acute systemic allergic reaction.

The CMS pays for allergy testing of Medicare beneficiaries and for their treatment through allergen immunotherapy. In this treatment, more commonly known as allergy shots, a physician administers gradually increasing amounts of an allergen to the patient over a period of several weeks. Upon reaching a maintenance level, the patient continues to receive injections on a regular basis, generally for at least 3 to 5 years. Allergy shots are normally reserved for those patients experiencing intolerable symptoms that do not respond to other therapies.

Allergists and immunologists, who specialize in the diagnosis and treatment of allergies, provide the bulk of allergen immunotherapy services for Medicare beneficiaries. In addition, many otolaryngologists (commonly known as ear, nose, and throat doctors, or ENTs) treat allergies, especially those affecting the respiratory system. General internists, family practitioners, and other physicians also provide some immunotherapy services.¹

The practice of immunotherapy varies among providers. In one common mode, a physician creates a "treatment set" by first creating a vial containing the specific antigen mix for a given patient. From that vial, the physician then makes multiple diluted vials to

¹In this report, we will refer to allergists and immunologists as "general allergists" and otolaryngic allergists as "otolaryngic allergists" or "ENT allergists."

provide lower concentration mixes that will be needed to “step up” the patient to the maintenance level.

Alternatively, a provider may create a treatment or dilution board as a first step in administering allergy shots (see Figure 1). As with treatment sets, boards contain multiple dilutions of antigens. Rather than dilutions specific to each patient, however, the provider creates diluted vials of each antigen serum used in his or her practice. The doctor may then draw particular antigens from the board and mix them in a multidose vial to be used for a given patient over multiple treatment sessions; alternatively, the doctor may then treat “off the board,” meaning he or she mixes and delivers each injection individually and directly from the board.

Figure 1: Dilution Board



Instead of using his or her own treatment sets or boards, a provider may choose to order treatment vials for each patient from a supplier, and perform only injection and observation services. No matter what practice is employed, antigen mixes have a finite “shelf life,” which is inversely proportional to their strength, and must be discarded if not used within a certain time.

Payment for Physician Services

Since 1992, Medicare has paid for physician services under a national fee schedule. Under this strategy, each medical procedure is assigned a relative value which measures the cost to perform the service compared to the cost to perform other covered services. Three factors determine the relative value of a service: physician work, practice expense, and malpractice expense. The physician work component, which is a measurement of the time, intensity of effort, and skill required for a service, constitutes 55 percent of the total value. Practice expense, which is 42 percent of the total, estimates the costs of doing business for a physician, including such expenses as staff salaries, overhead, and supplies. Malpractice expense, i.e., the cost of physician liability insurance, represents the remaining 3 percent. Payment for a given service is a function of its relative value and a geographic index based on the location where the service was provided.

The American Medical Association’s Relative Value Update Committee was formed in 1991 to provide input on relative value units. In addition to recommending work inputs, the Committee comments on CMS’ proposed interim relative value units. The Committee is comprised of 29 members, most of whom represent major specialty societies, including otolaryngology, but not allergy/immunology. An advisory commission embodying each of the 98 specialties in the Association’s House of Delegates provides support for the Committee.

The Association plays another important role in fee schedule payments by appointing the panel that maintains the list of Current Procedural Terminology (CPT) codes which are used by providers to bill Medicare. The CMS adopted CPT codes in 1983 as part of its Common Procedure Coding System. More than 7,000 codes appear in the current edition of the CPT manual.

CPT Code 95165

Medicare allowed approximately \$98 million in charges for allergen immunotherapy codes in 2000. Nearly half of these charges, \$47 million, were for CPT code 95165, *professional services for the provision of antigens for allergen immunotherapy; single or multiple antigens, per dose*. This code describes the preparation of antigen serums for use in immunotherapy, but not their injection. General allergists submitted about two-thirds of the claims for CPT code 95165, and ENT allergists account for about 20 percent. Most of the remainder come from internists, general practitioners, family doctors, and various group practices. Although per unit allowed charges are fairly constant across different specialties, ENT allergists bill more units (and receive greater reimbursement) per claim than other specialties (see Table 1).

Table 1: Median 95165 billing by specialty

Specialty	Year	Allowed amount	Units	Per unit allowed amount
General allergists	2000	\$20.00	2.00	\$8.35
	2001	\$24.90	3.00	\$9.00
ENT allergists	2000	\$70.00	10.0	\$8.14
	2001	\$80.00	10.0	\$8.65
Other physicians	2000	\$22.36	2.00	\$8.36
	2001	\$21.90	2.00	\$8.82

**Figure 2:
Vial and
10 cc Syringe**



The interpretation of CPT code 95165 has been controversial. The code is unlike others in that it includes the concept of a ‘dose,’ which is not defined in the CPT manual. Traditionally, providers and payers defined a dose as the amount of antigen given in a single injection. In May 1998, CMS updated the carrier manual to define a dose as “the total amount of antigen to be administered to a patient during one treatment session, whether mixed or in separate vials.” Private payers, however, did not adopt this change; as a result, they paid 590 percent more per unit of CPT code 95165 than Medicare in 1999.² After this change was instituted, the Relative Value Scale Update Committee recommended that CMS return to the traditional definition for the 1999 fee schedule update. At the time, though, CMS did not feel a revision was appropriate because the Committee failed to comment on the direct practice expense inputs to the code. In November 2000, after receiving many comments from specialty organizations, CMS revised the inputs for CPT code 95165. In this revision, effective January 1, 2001, CMS defines a dose, for billing and practice expense calculations, as “a one cc aliquot [part]

²In fact, according to OIG analysis, private payers pay significantly more for nine allergen immunotherapy codes than Medicare, and significantly less for the CPT injection codes 95115 and 95117.

from a single multidose vial.’³ All practice expense inputs for CPT code 95165 are based on this definition, although no allocation is made for resources and work used to create treatment or dilution boards.

METHODOLOGY

Survey

We used a mail survey as the primary tool to accomplish the purpose of this study. The survey solicited mainly factual information on physicians’ practice patterns, including the time and resources used in preparing and administering allergy shots. We conducted extensive pre-testing of the survey instrument to ensure that we were using accurate and understandable terminology and to improve the clarity and logical flow of the questions.

We used a stratified random sample to select physicians to whom we sent the survey. From 2001 National Claims History (NCH) data, we defined our universe as physicians appearing on claims for CPT code 95165 allowed in an office setting. These physicians were divided into three strata: allergists and immunologists in the first stratum, otolaryngologists in the second, and general practitioners, family doctors, internists, and group practices and clinics in the third. Together, these three strata accounted for 95 percent of the claims submitted for CPT code 95165 in 2001.

We randomly selected 102 physicians from each stratum to participate in the survey. To obtain names and addresses for these physician, we ran a match against CMS’ unique provider identification number, or UPIN, master file and did our own internet research, which resulted in 301 valid names and addresses. We sent surveys to each of these addresses and received

Table 2: Sample and response rate

Stratum	Physicians in universe	Physicians in sample	# of surveys mailed	# of responses	# usable
1 (Allergists)	2348	102	101	69	69
2 (ENTs)	1974	102	101	65	61
3 (Others)	1229	102	99	52	47
Total	5551	306	301	186	177

responses from 186 (60.8 percent). Nine of these responses,

³Medicare does not accept separate CPT codes for physicians who treat off the board. These physicians submit claims based on the same 1 cc standard.

however, did not contain usable information. Responses were weighted according to each stratum's representation in the population. Our sample design and response rate were adequate to make projections to the universe with a reasonable degree of precision. Table 2 (previous page) shows selected information for the three strata.

Responses to each survey question varied greatly; for instance, respondents reported using from 1 to 38 antigens in a multidose vial and injecting from .05 cc to 4.0 cc of serum in each allergy shot. Given this variation, we used the median as representative of a 'typical' practice, since it is less affected by extreme values than the arithmetic mean. We received a large number of zero responses concerning questions about the amount of clinical staff time spent creating boards and vials and about the number of boards prepared in a year. For these questions, the median may not be an appropriate representation of a typical practice, so we include the mean as well. In all such cases, however, we were able to make comparisons among subgroups only with mean values.

Non-respondent analysis. We used chi-square tests and linear regression to compare non-respondents to respondents in terms of their stratum, year 2001 claims volume (of CPT code 95165), Medicare patient volume, mean number of services per claim, mean number of services per patient, and population and urban/rural characteristics of the county in which they practice. None of these tests was significant at the 95 percent confidence level.

Other Data

We interviewed 25 of the 27 Medicare carriers about guidance they received from CMS and any instructions they issued to their physician communities. We asked for copies of any written guidance distributed to providers, which we evaluated for completeness and clarity. Two carriers did not respond to numerous interview requests.

In addition, we spoke to several representatives of national allergy associations and consulted with practicing physicians. Several local allergists allowed us to observe the preparation of antigens and helped us develop our survey instrument. Lastly, we reviewed laws, regulations, policy letters, and other materials related to CPT code 95165.

This study was conducted in accordance with the *Quality Standards for Inspections* issued by the President's Council on Integrity and Efficiency.

FINDINGS

We primarily used a national survey of a random sample of practitioners of allergen immunotherapy to develop the findings of this report. In addition to the survey, we interviewed staff and evaluated guidance documents from Medicare carriers. Lastly, we reviewed policy and regulations concerning CPT code 95165 and spoke with allergen immunotherapy providers. Based on our analysis, we found that current practice expense calculations do not accurately reflect typical practices among immunotherapy providers. Also, while most providers are aware of the new definition of a dose for CPT code 95165, most say it does not correspond with the way they provide allergen immunotherapy.

Physicians typically use dilution boards to prepare multidose vials

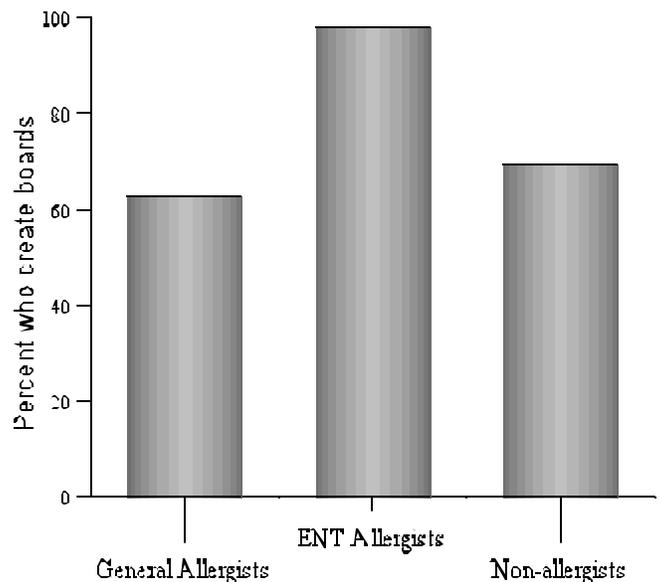
Most physicians create several boards per year

More than 75 percent of providers indicate that they create boards either for directly treating patients or as a first step in creating multidose vials. Nearly all ENT allergists use boards in some fashion, compared to 63 percent of general allergists and 69 percent of other physicians.

Regardless of specialty or mode of practice, the typical provider prepares 3.6 (*median; mean=7.6*) boards per year. Physicians in counties located entirely in metropolitan areas tend to prepare boards more often than their less urban counterparts, as do physicians who at least sometimes treat off the board. In addition, physicians who provide allergen immunotherapy, but do not identify themselves as allergists, produce fewer boards than ENT or general allergists.⁴

Physicians and their staff spend about 46 minutes (*median; mean=93 minutes*) creating each board. The greatest amount of time is attributed to registered nurses, though physicians, licensed vocational

Figure 3: More ENT allergists create boards



⁴We found no evidence of a relationship at the 95 percent confidence level between the number of boards prepared and the number of the physician's patients on allergen immunotherapy.

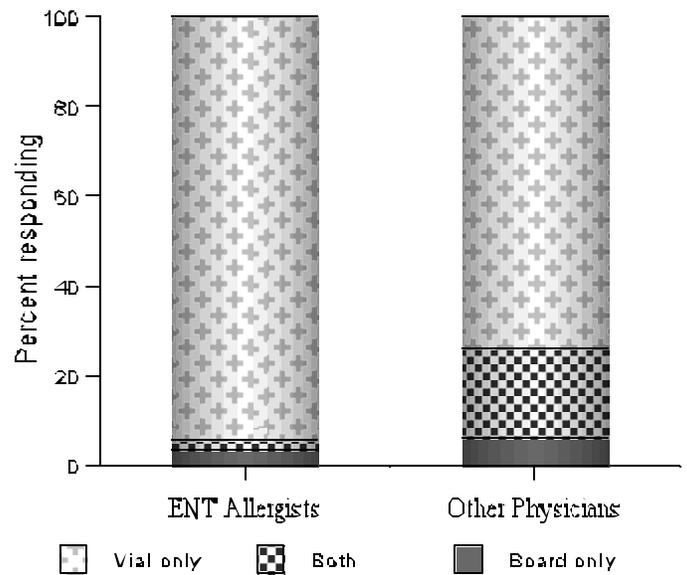
nurses, medical assistants, and other staff, such as allergy technicians, sometimes contribute.⁵ Otolaryngic allergists spend significantly more time (167 minutes) preparing each board than do general allergists (66 minutes) or other specialties (63 minutes). We found no evidence, however, that the amount of staff time needed is associated with treating off the board. In addition, physicians who submitted a greater number of claims of CPT code 95165 tend to take more time preparing boards. This seems logical in that high-volume practices may require more antigens or larger volumes of antigen on each board.⁶

Fewer than 20 percent of providers treat off the board

Most physicians prepare multidose vials of allergen immunotherapy from a treatment or dilution board rather than treat off the board. About 81 percent of physicians provide immunotherapy exclusively from multidose vials. Another 14 percent use a combination of treating off the board and vials, while only 5 percent treat exclusively off the board. Treating off the board is much less common among ENT allergists (5.45 percent) than either general allergists (26.6 percent) or other specialties (24.8 percent).

Administering shots directly off the board is a practice quite different from first creating multidose vials for each patient. As such, treating off the board is an important factor in the outcomes of several other survey questions. Time spent preparing vials, the number of injections given per treatment session, and a provider's response to the January 2001 change all are influenced by this practice. Each of these effects will be discussed later in this report.

Figure 4: Fewer ENT allergists treat off the board



⁵A single physician rarely uses all of these types of staff, but each type is used by at least one physician in the sample.

⁶This effect is independent of the specialty of the physician.

More than three-fourths of physicians purchase their allergen immunotherapy supplies individually

An overwhelming proportion (85.5 percent) of practitioners purchase immunotherapy supplies individually. Even in group and clinic settings, more than three-quarters of physicians purchase their supplies independently. Physicians who submit a relatively large number of claims for CPT code 95615 (more than 50 in the first 6 months of 2001) are more likely to buy supplies on their own. Only one respondent to the survey had a purchasing arrangement with other physicians outside his or her group.

We followed up with nine physicians to determine why they did not enter into group purchasing arrangements. Almost all identified the lack of standardized antigen serum across suppliers as a primary reason for maintaining individual arrangements. They explained that serums differ across manufacturers and techniques for mixing antigens and diluent are directly related to type of serum obtained from a specific supplier. Therefore, it would be difficult to get each physician in a group purchasing arrangement to agree to the same supplier. According to our interviewees, since most physicians are able to negotiate some discounts on allergen immunotherapy supplies purchased individually, the difficulty in designing a group arrangement would likely outweigh any potential cost savings. In fact, nearly half of those interviewed had considered group arrangements at some point, but had ultimately decided against them.

Resources used in allergen immunotherapy differ from CMS assumptions

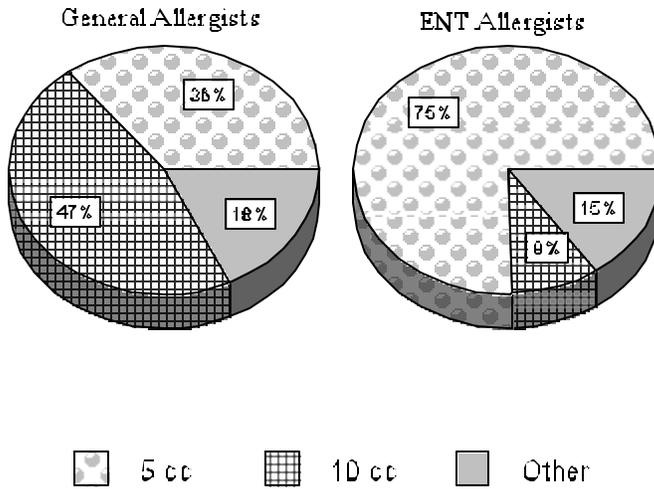
The one cc aliquot accepted by CMS as a typical injection of CPT code 95165 is much too large, according to our survey. We found that the median volume of an injection is about 0.47 cc, less than half the figure in the *Federal Register* (FR).⁷ About 48 percent of physicians typically give injections of .5 cc, and another 31 percent inject even smaller amounts. The specialty of the physician has a strong relationship with the size of injection they

Table 3: Resources used in a typical practice differ from assumptions

Resource	CMS Estimate	Survey Estimate
Staff time	2.2 minutes	3.0 minutes
Vial size	10 cc	4.90 cc
Number of antigens in vial	5	7.95
Antigen volume as percentage of total	100%	59%
Volume of injection	1.0 cc	0.47 cc

⁷65 FR 65393, November 1, 2000.

Figure 5: Vial size varies by specialty



of physicians are almost evenly divided between those that use vials of less than 5 cc capacity and those that use vials of greater than 5 cc, but less than 10 cc. A few respondents said they use vials even larger than 10 cc. The size of vial that is used is strongly correlated with the specialty of the provider, as shown in Figure 5. Without regard to specialty, the median capacity of a vial is 4.90 cc.

The *Federal Register* publication assumes that 5 antigens are present in a typical multidose vial, without any diluent. According to our survey, a typical multidose vial contains approximately 8 antigens. Providers in a clinic setting use more antigens than others: 11.7 on average, compared to about 7.8 for solo practitioners or physicians in a single-specialty group. In addition, our survey indicates that a typical multidose vial contains only about 59 percent antigen by volume; the rest is diluent.

According to our respondents, the current rule does not sufficiently account for the time needed to create multidose vials. The new definition of a dose incorporates 2.2 minutes of clinical staff time as a practice expense. Our survey data suggests that preparing antigens in a multidose vial requires closer to 3.0 (median) to 4.5 (mean) minutes of staff time per dose. Our limited visits to physicians' offices, however, suggest that this figure may be inflated; additional direct observation would be needed to confidently report the amount of time required. As with boards, our respondents attribute the greatest portion of time spent creating vials to registered nurses. Physicians who sometimes treat off the board in addition to using multidose vials dedicate less staff time (2.9 minutes per dose) to creating a vial than those that exclusively use vials (4.8 minutes per dose).

administer; 91 percent of ENT allergists give injections of .5 cc or less, compared to about 72 percent of other physicians. On average, physicians of all specialties give 1.6 injections per treatment session. Physicians who treat off the board tend to give more injections, an average of 2.1 compared to 1.5 for those who do not.

The January 2001 definition of a dose assumes physicians typically draw doses from a 10 cc multidose vial. We found that about 51 percent of physicians use a 5 cc multidose vial in their practice while only 31 percent use a 10 cc vial. The remaining 18 percent

Almost 75 percent of providers are aware of the new definition of a dose

Providers primarily rely on their specialty society or association for information

Nearly three-quarters of physicians who provide allergen immunotherapy are aware of the January 2001 revision. A positive relationship exists between the number of patients for whom the physician provides immunotherapy and their probability of being aware of the revision. Also, general allergists are more likely to know of the revision than ENT allergists, who, in turn, are more likely than other providers to be aware of the change.

Specialty societies are important sources of information for providers. Fifty-nine percent of physicians first learned of the change from their society. In contrast, only 29 percent first learned of the change from their Medicare carrier. Non-allergists make up a large part of this group, reflecting their low rate of membership in allergy-related specialty societies.

Although relatively few physicians learned of the revision from their carrier, the 25 carriers we contacted all had received guidance from CMS on the new rule and had issued a provider bulletin explaining the change. Approximately half of the carriers we interviewed sent a newsletter to their physicians outlining the change and posted notices on their physician web site; the remainder only mailed a newsletter or bulletin. The majority of carriers (22 of 25) issued these instructions between November 2000 and January 2001, though one carrier did not issue formal instructions until June 2001.

Most of the guidance issued by carriers reiterated the CMS guidance almost verbatim. We found most of the written notices to be clear and easy to understand, although four notices failed to adequately highlight information regarding CPT code 95165. We found that one notice was particularly confusing because it combined information for CPT code 95165 with information for CPT code 95115. On the other hand, one carrier offered several clinical examples in its bulletin to help clarify the new rule.

The revised definition has led some physicians to change billing and medical practices

Most physicians did not change their billing or medical practice because of the new definition. Approximately 57 percent of physicians were either unaware of the revision or did not make any changes in response to it. Several of the latter group explained that they had already been billing Medicare according to the January 2001 definition before it went into effect.

Fifty-four percent of physicians who were aware of the new definition changed their billing as a result. About one-quarter of these physicians say they now bill 1 cc as a dose, as outlined in the *Federal Register*.

Another 16 percent report that they no longer bill for dilutions. The remainder either did not specify the particular change or indicated a change other than the two listed above.

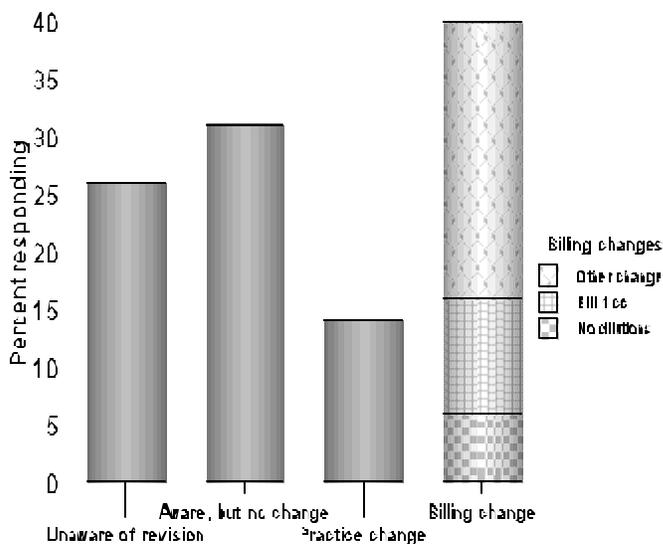
Some experts expressed concern that the revision as published in the *Federal Register* would cause physicians to alter their medical practice as well as their billing. This concern is borne out somewhat by our data: almost 20 percent of physicians who were aware of the new definition say they have changed how they administer allergen immunotherapy in response. Some of these explained that they now administered 1 cc as a dose for each Medicare patient, while others altered other aspects of their practices. The CMS, however, did not intend to dictate the practice of medicine and, in fact, issued an update to the carrier manual in September 2001 to clarify this point.

Only 11 percent of practitioners prefer the new definition of a dose

According to our survey, more practitioners (46.7 percent) prefer the traditional definition of a dose, the amount of antigen administered in a single injection, than any other. Only about 11 percent feel that the definition should be based on a particular volume of antigen, as it is currently. Seventeen percent of practitioners said that the definition of a dose should revert to the 1998 guidance of the total amount of antigen administered in an office visit.

Many respondents, as well as physicians to whom we spoke in preinspection, offered specific recommendations for an improved definition. Several believe one of the main problems with both the past and current definitions is they do not account for time and

Figure 6: Physicians' response to revision



resources used to create treatment and dilution boards. Others suggest that the definition lacks consideration for the different strength dilutions used in creating vials. Still others say that it is more appropriate to base the definition on the number and strengths of allergenic extracts used rather than a volume of serum, which could contain any number of allergens. Several providers expressed sympathy for CMS' dilemma in defining a dose amid a wide variety of practices.

CONCLUSION

The CMS commented on the working draft of this report and concurred with our findings. They indicated, however, that CMS will take no action at this time to address CPT code 95165. The CMS believes that using a 10 cc vial and 1 cc aliquots as the basis for practice expense calculations are not significantly different from using a 5 cc vial and 0.5 cc aliquots. Also, according to CMS, allocating the time and resources spent creating a dilution board to each individual dose would result in a minuscule, if any, change in payment. The clinical staff time required per dose, as stated in the report, requires more study before it could be used as a basis for changing reimbursement. The amount of antigen in a vial, however, is a practice expense issue that CMS has indicated they may address in the future.

With CMS' comments in mind, we conclude that although the agency did not have accurate data when it calculated the practice expense component for CPT code 95615, there is no compelling need for immediate change. Therefore, CMS could use the information in this report to help refine the practice expense inputs for CPT code 95165 as they see fit, perhaps in conjunction with the next meeting of the Practice Expense Advisory Committee. Since some physicians modified their practice based on the changes in reimbursement, CMS could continue to emphasize that physicians need modify only their billing to comply with the new definition in any guidance it plans to offer in the future. We also noted that most physicians rely on their specialty societies, rather than CMS or its carriers, for information about Medicare policy changes. Therefore, to ensure physicians are getting accurate information, CMS and the carriers may want to work directly with the societies to explain any policy changes and revisions.

Glossary of Terms

Aliquot - A part of a whole which is a proper divisor of that whole [Webster's]; used in the *Federal Register* definition of a dose to mean an extract from a multidose vial.

Allergy - Reactions of the immune system to substances that, in most people, cause no symptoms. [AAAAI website]

Allergen - A foreign substance that leads to allergies by starting an immune response. [AAAAI website]

Anaphylaxis - A medical emergency which involves an acute systemic allergic reaction. [AAAAI website]

Antigen - A substance that can trigger an immune response. [AAAAI website]

Diluent - A liquid used to dilute the strength of an antigen serum.

Immunotherapy - (“allergy shots”) A form of preventive and anti-inflammatory treatment of allergy. Immunotherapy involved gradually increasing doses of allergen(s), causing a decrease in immune sensitivity to the allergen. [AAAAI website]

Maintenance level - The maximum antigen concentration and volume tolerated by a patient and at which they will be given immunotherapy over a period of time.

Multidose vial - A vial containing antigen serum intended to be used for multiple injections of a particular patient.

Treatment or dilution board - A board used to store multiple vials of antigen serums at various concentrations, for use either in directly treating patients or in creating multidose treatment vials which are then used to treat patients.

Treat off the board - Mix and inject shots directly from a treatment board rather than first creating multidose vials.

Treatment set - A set of multidose vials, prepared for a single patient, which is made up of vials at various concentrations and used to “step up” the patient to a maintenance level.

Confidence Intervals for Selected Statistics

The following table shows the point estimates and 95 percent confidence intervals for selected statistics, in the order they appear in the findings. In addition, the table shows point estimates and confidence intervals for both the median and mean, where applicable. These calculations are weighted according to the stratification described in the methodology.

Statistic	N	Point Estimate	95 Percent Confidence Interval
FINDING I			
Percent of physicians who use boards	177	75.37%	69.24% - 81.49%
Mean number of boards prepared per year	146	7.56	4.46 - 10.66
Median number of boards prepared per year	146	3.57	2.87 - 3.73
Mean time (minutes) spent preparing each board	154	92.50	75.34 - 109.67
Median time (minutes) spent preparing each board	154	45.71	28.37 - 67.49
Percent of physicians who treat exclusively using multidose vials	166	80.66%	74.81% - 86.50%
Percent of physicians who mix using vials and boards	166	14.12%	8.98% - 19.26%
Percent of physicians who treat exclusively off the board	166	5.22%	1.87% - 8.58%
Percent of physicians who purchase supplies independently	176	85.53%	80.57% - 90.48%
Percent of physicians in group/clinic settings who purchase supplies independently	91	78.16%	69.79% - 86.53%
FINDING II			
Mean volume (cc) of injection	172	.578	.505 - .651

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Median volume (cc) of injection	172	.470	.463 - .477
Percent of physicians who inject .5 cc	172	47.57%	40.18% - 54.96%
Percent of physicians who inject < .5 cc	172	30.80%	23.93% - 37.66%
Mean number of injections per session	172	2.36	1.99 - 2.73
Median number of injections per session	172	1.59	1.50 - 1.69
Percent of physicians who use a 5 cc vial	155	50.84%	43.22% - 58.47%
Percent of physicians who use a 10 cc vial	155	31.13%	24.09% - 38.18%
Percent of physicians who use a <5 cc vial	155	9.54%	4.85% - 14.24%
Percent of physicians who use between a 5 and 10 cc vial	155	7.03%	3.14% - 10.92%
Percent of physicians who use a >10 cc vial	155	1.45%	<= 3.07%
Mean vial capacity (cc)	155	6.91	6.33 - 7.49
Median vial capacity (cc)	155	4.90	4.83 - 4.97
Mean number of antigens per vial	155	9.84	8.84 - 10.83
Median number of antigens per vial	155	7.95	7.61 - 9.91
Antigen as a proportion of vial volume	151	58.9%	55.55% - 61.78%
Mean time (minutes) to create a dose	147	4.45	3.69 - 5.22
Median time (minutes) to create a dose	147	2.98	2.91 - 4.05
FINDING III			
Percent of physicians aware of revision	177	73.84%	67.81% - 79.88%
Percent of physicians who learned of revision from their specialty society	122	58.93%	50.50% - 67.35%
Percent of physicians who learned of revision from their carrier	122	29.03%	21.26% - 36.80%
Percent of physicians who were unaware of revision or did nothing in response	177	56.53%	49.33% - 63.72%

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Percent of physicians who were unaware of revision	177	26.16%	20.12% - 32.19%
Percent of physicians who did nothing in response	177	30.37%	23.53% - 37.21%
Percent of physicians who changed practice	177	14.12%	8.87% - 19.37%
Percent of physicians who changed billing	177	39.52%	32.39% - 46.65%
Percent of <i>aware</i> physicians who changed billing	122	54.21%	45.45% - 62.97%
– percent of above who now bill 1 cc as dose	71	23.39%	13.46% - 33.32%
– percent of above who no longer bill dilutions	71	16.26%	7.37% - 25.09%
– percent of above who made some other change	71	63.63%	52.48% - 74.78%
Percent of <i>aware</i> physicians who changed practice	122	19.37%	12.33% - 26.41%
Percent of physicians who prefer traditional definition	173	46.75%	39.40% - 54.09%
Percent of physicians who prefer volume-based definition	173	11.15%	6.41% - 15.90%
Percent of physicians who prefer 1998 definition	173	17.31%	11.59% - 23.03%

P-values for Selected Comparisons

The following table 1 shows the results t-tests for selected comparisons. Where we conducted pairwise tests of multiple groups, the particular groups tested are displayed, as is the threshold for determining significance (calculated using the Bonferroni method.) We used $\alpha=0.05$ for all tests.

Comparison	Group	Statistic	Threshold	Result
Mean number of boards by urban/rural character of county	<i>Rural counties</i>	2.93	n/a	significant
	<i>Urban counties</i>	8.82		
Mean number of boards by specialty, pairwise	<i>(1) General allergists</i>	9.51	0.0167	vs.(3) - significant
	<i>(2) ENT allergists</i>	6.96		vs.(3) - significant
	<i>(3) Non-allergists</i>	2.43		-
Median number of injections by treating off the board	<i>Not off the board</i>	1.51	n/a	significant
	<i>Off the board</i>	2.06		
Number of antigens by type of practice	<i>(1) Solo practitioner</i>	7.81	0.00833	vs.(3) - significant
	<i>(2) Group practice</i>	7.80		vs.(3) - significant
	<i>(3) Clinic</i>	11.74		-

The next table shows a sample chi-square for the comparison between physicians specialty and treating off the board.

Specialty	Number of respondents	
	Not off the board	Off the board
General Allergist	60 (<i>weighted=1278.77</i>)	23 (<i>weighted=463.63</i>)
ENT Allergist	52 (<i>weighted=1006.35</i>)	3 (<i>weighted=58.06</i>)
Non-allergist	20 (<i>weighted=292.14</i>)	8 (<i>weighted=96.39</i>)

Chi-square for treating off the board by specialty = 0.0004895 - significant

ACKNOWLEDGMENTS

This report was prepared under the direction of Paul A. Gottlober, Regional Inspector General for Evaluation and Inspections in the San Francisco Regional Office. Other principal Office of Evaluation and Inspections staff who contributed include:

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This inspection team would like to thank all the respondents to the survey. We would like to particularly thank the physicians who assisted us in designing the survey instruments and reviewing the background section of the report.

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